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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/527,312

11/08/2005

Teshiya Fujisato

AKA-282

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08/14/2008

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.

2200 CLARENDON BLVD.

SUITE 1400

ARLINGTON, VA 22201

EXAMINER

SAUCIER, SANDRA E

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

08/14/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/527,312 | <b>Applicant(s)</b><br>FUJISATO ET AL. |  |
|                              | <b>Examiner</b><br>Sandra Saucier    | <b>Art Unit</b><br>1651                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 June 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

DETAILED ACTION

Claims 1–6 are pending and are considered on the merits.

***Claim Rejections – 35 USC § 103***

Claims 1–6 remain rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/09287 [N].

The claims are directed to a process comprising applying ultrahigh hydrostatic pressure in the range of 5000–15000 atm for at least 10 minutes to a tissue/organ in a liquid medium and washing the tissue.

WO 01/09287 discloses the use of the application of ultrahigh hydrostatic pressure above 100 MPa for 1 second to 3 hours or more to human or animal tissues prior to transplantation, pages 13–14 of the translation.

To the extent that the reference differs from the cited prior art, these differences are considered to be optimization of the parameters of the process and well within the purview of those of skill in the art.

One of ordinary skill in the art would have been motivated at the time of invention to make modifications in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

***Response to Arguments***

Applicant's arguments filed 6/5/08 have been fully considered but they are not persuasive.

Applicant argues that no teaching of at least a 10 minute exposure to the pressure is present in the document of WO 01/09287. Please see WO 01/09287 at page 13 where times of up to 60 minutes are preferred. Thus, the generic portion of the document supports time periods of at least 10 minutes.

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Applicant argues that WO 01/09287 teaches that pressures above 225 MPa kills cells and influences mechanical properties of bone; therefore, no motivation to increase the pressure above 225MPa exists in the document. Please note that while for certain tissues (bone) and cells the teaching of the cited prior art is a 15% decrease in the breaking load of bone exposed to 225MPa, and a large decrease in viability of cells (a) the claims are not commensurate in scope with the argument and (b) the claims do not require that the bone does not have different mechanical properties from the natural, untreated bone tissue or that the cells or organs be alive and functioning after treatment. Please note that the phrase “whereby the connective tissue thereof is rendered isolatable” is not an active step, but merely a statement of ability which would inherently flow when a pressure treatment is applied. Thus, for at least these reasons, the arguments are unpersuasive and are not commensurate in scope with the showing.

Art cited as being of interest, but not against the claimed method at this time. Meyer-Pittroff “High Pressure Applications in Medicine” and DE 299 13 526 [N].

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). It is applicants' burden to indicate how amendments are supported by the ORIGINAL disclosure. Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sandra Saucier/  
Primary Examiner  
Art Unit 1651